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Standards and Technology Leadership"

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14. ABSTRACT This award enables the MGH Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to deliver solutions to enable medical device manufacturers, users, and the regulatory community to improve patient safety and healthcare efficiency through interoperable medical technologies. During 2015-2016, we played a leadership role working on interoperability standards with ASTM, AAMI, ISO, and the AAMI/UL JC2800 developing standards for certifiable safety of medical device interfaces. We developed core content for an ICE Data Logger ("black box recorder") draft standard that was submitted to AAMI as a New Work Item Proposal. MD PnP efforts have enabled significant changes to the trajectory of standards and technologies to apply interoperability to support patient safety and innovation. Other standards and products are building on the ICE standard, and will inform changes to future revisions to ICE and to the ICE Data Logger standard. We organized and disseminated clinical and system requirements to facilitate adoption by device manufacturers, thereby providing products for procurement by the DoD and others. We led the submission to the FDA of a second pre-IDE supplement for interoperable medical devices (published on our web site), and subsequent responses to FDA requests. We have leveraged our collaborative work with federal agencies, academia, industry, and standards development organizations to provide leadership, subject matter expertise, and technical content to advance interoperability.					
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**Annual Report: Medical Device Plug-and-Play Interoperability
Standards and Technology Leadership
Award Number W81XWH-09-1-0705
Principal Investigator: Julian M. Goldman, MD
Period of Performance: 21 September 2015 – 20 September 2016**

Introduction

A May 2004 symposium jointly sponsored by TATRC and CIMIT kicked off what became the Medical Device “Plug-and-Play” (MD PnP) interoperability program. Initially focused on creating a standardization framework for interoperability of medical devices in the Operating Room of the Future (ORF), the program collected clinical requirements from anesthesiologists, surgeons, and clinical engineers, and began to define an agenda for standards development. Within a year, we acknowledged that the need for interoperability encompasses the full continuum of healthcare environments (not limited to the OR), and we developed a strategy to accelerate the development of interoperability technologies, as well as standards. This strategy addressed the need for a “sandbox” laboratory environment to facilitate the testing of devices and technologies with proposed standards; development of a “plug-and-play” system architecture; collaboration with regulatory agencies; leveraging standards and technology to address vendors’ liability and regulatory concerns; and assuring the clinical relevance of all proposed interoperability solutions.

TATRC support, through a prior BAA and conference grants, has enabled the MD PnP interoperability program to develop key capabilities, to identify, access, and share numerous available resources, and to build collaborations to achieve MD PnP-identified objectives. TATRC’s commitment has enabled us to attract additional program funding from Partners Information Systems, CIMIT, NSF, NIST, and NIH. We have created a \$1M medical device interoperability laboratory in Cambridge, MA as a vendor-neutral, interdisciplinary shared resource. We have developed clinical use cases demonstrating the capability of medical device interoperability to improve patient safety, and have exhibited these demonstrations at national meetings and held demonstrations for international audiences in our MD PnP Lab. In 2007, we held our first international conference on “Improving Patient Safety through Medical Device Interoperability and High Confidence Software”, jointly sponsored by TATRC and NSF.

Significantly, core program support from TATRC enabled us to lead the writing of the first medical device integration system safety standard – the Integrated Clinical Environment (ICE) standard, ASTM F2761—Part 1, which includes functional (or logical) architecture and risk mitigation strategies for networked, patient-centric interoperable medical devices. In addition, we led a successful collaborative effort involving four major healthcare delivery organizations to develop and adopt sharable interoperability contracting language for use in the procurement of medical devices and related equipment. We facilitated the endorsement of medical device interoperability for improving patient safety by fourteen medical societies (including the American Medical Association). We additionally worked with three companies on DoD SBIR projects to develop a first-responder ICE Supervisor. TATRC BAA support has been instrumental in providing “program glue” to effectively leverage these highly interdependent and synergistic activities to realize program objectives.

With the FDA and Continua Health Alliance, MD PnP through CIMIT planned and co-sponsored a three-day workshop on Medical Device Interoperability in January 2010. The workshop was attended by over 200 participants from industry, health care, and federal agencies. There has since been a follow-on working group, which meets regularly under MD PnP leadership, to

address safety and regulatory concerns for integrated medical device systems. The FDA organized another meeting on device interoperability with AAMI in 2011, and, in 2012-2013, the FDA initiated a Medical Device Interoperability Coordinating Council to bring together various groups working on different aspects of interoperability. MD PnP played a leadership role in these activities.

Body of Report

The MD PnP Program has become a recognized leader in demonstrating clinically derived technical solutions for improving patient safety and healthcare efficiency through medical device interoperability. Interoperability will enable the creation of complete electronic health records and will introduce advanced capabilities, such as clinical error resistance, into networked medical device systems. We are producing a standardization framework consisting of a functional architecture and requirements for implementing standards in a manner that will support safe interoperability for effective clinical deployment. This requires critical evaluation (or “gap analysis”) of potentially suitable candidate standards, as well as the modification of existing standards and the development of new standards for implementation in the MD PnP “standardization framework.” By leveraging available standards, we expect to accelerate the MD PnP standards framework development so that useful candidate standards can be vetted and demonstrated. This includes partnering with industry and the FDA to define interoperability-related hazards and mitigation thereof to help inform regulatory science for networked medical device systems. This has also involved developing the MD PnP Laboratory as a “sandbox” populated with medical devices and test equipment to serve as a vendor-neutral environment to evaluate proposed standards and technologies. Building on our accomplishments to date, we have sought to leverage areas of traction around five key themes identified for this work:

- Standards Development
- Clinical and Engineering Requirements for Safe Medical Device Interoperability
- Interoperability and Security Requirements for Medical Device Procurement
- Regulatory Science for Safe Medical Device Interoperability
- Management of External Collaborations

Since the program's inception, more than 900 clinical and engineering experts, as well as representatives of more than 120 industrial and academic institutions, have participated in our plenary workshops / conferences, working group meetings, lab demonstrations, and focus groups to contribute to ongoing program activities that helped shape the common goals. Recent collaborators include participants from the VHA, FDA, NIST, TATRC; computer and information science groups at University of Pennsylvania, University of Illinois at Urbana-Champaign, and Kansas State University; Intel, RTI, Biogen, Medtronic, Draeger Medical Systems, Philips Healthcare, GE Healthcare, and DocBox Inc.; NSF programs on CPS (Cyber Physical Systems) and SCH (Smart and Connected Health), and the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women's Hospital, and Partners HealthCare Information Systems).

Option-Year 3 activities under this award have built upon all of our MD PnP program work to date and reflect our vision of progressing medical device interoperability standards, whether specifically ICE-related or more generally applicable, and continuing to develop and make available the clinical requirements for safe medical device interoperability, helping healthcare delivery organizations in general and the DoD in particular with strategies for the procurement of interoperable medical devices, working with the FDA to develop the regulatory science related to integrated medical device systems, and continuing to build the community of interest that will

lead to widespread availability and adoption of medical device interoperability for the improvement of patient safety and clinical workflow efficiency. Our work has reached a level of federal interest, national and international recognition, and resource development that underscores our ability to provide strong clinically based leadership in all of these areas.

Aims 2, 5, 7, 8, 10, 11, and 12 were completed for purposes of this award during Option-Year 2. For Option-Year 3 of this grant, the following set of aims was agreed on with TATRC, consisting of updated versions of original Aims 1, 3, 4, 6, and 9:

Standards Development

- **Aim 1:** Continue to work closely with standards committees and standards development organizations to provide subject matter expertise and functional examples of medical device interoperability, and shepherd the transition of F2761-09(13), the “ICE” standard, from ASTM to AAMI as Committee F29 is sunsetted. (Dr. Goldman is chair of ASTM Committee F29, where the ICE standard was developed, and Co-Chair of the AAMI Interoperability Working Group.)
- **Aim 3:** Provide interoperability demonstrations and education at the AAMI annual meeting and standards meeting in June 2015 in Denver, CO; based on the feedback received at these meetings, refine our technology and document our findings.

Clinical and Engineering Requirements for Safe Medical Device Interoperability

- **Aim 4:** Implement workflow to more effectively support standards activities using our research data, and demonstrate these capabilities for feedback at the next AAMI/UL JC2800 meeting on December 7-10, 2015 in Newport Beach, CA.

Interoperability and Security Requirements for Medical Device Procurement

- **Aim 6:** For the adoption roadmap, obtain additional input from MD PnP program collaborators who have joined to form the ICE Alliance, managed by the IEEE-ISTO.

Regulatory Science for Safe Medical Device Interoperability

- **Aim 9:** Based on the successful second FDA pre-IDE submission, respond to the FDA’s request that we formulate use cases to convey the differences between pair-wise and component-wise interoperability.

Management of External Collaborations

All aims were completed for purposes of this grant, but external collaboration activities are an ongoing part of the MD PnP Program work.

Research Accomplishments

Standards Development, Aim 1: Continue to work closely with standards committees and standards development organizations to provide subject matter expertise and functional examples of medical device interoperability, and shepherd the transition of F2761-09(13), the “ICE” standard, from ASTM to AAMI as Committee F29 is sunsetted. (Dr. Goldman is chair of ASTM Committee F29, where the ICE standard was developed, and Co-Chair of the AAMI Interoperability Working Group.)

The MD PnP Program has continued to play a leadership role in medical device interoperability standards initiatives and to work closely with several standards development groups in support of safe and clinically meaningful interoperability, including providing subject matter expertise and functional examples of interoperability: the AAMI/UL Joint Committee (JC) 2800 standard

for certification of safe medical device interoperability, the AAMI Interoperability Working Group (IOWG), and other device-specific standards, such as the ISO 80601-2-61 standard for pulse oximetry.

The “ICE” standard – ASTM F2761-09(13) – describes a logical or functional architecture for platform-based medical device interoperability to enable the use of “apps” and devices to support innovation in clinical care, research, operations, and biomedical device management, and to enhance the security of the integrated clinical environment.

ASTM F2761 was developed by ASTM Committee F29, based on three years of MD PnP research supported by DHA. In 2014-15 ASTM made plans to sunset Committee F29, which required shepherding its standards work to a new Standards Development Organization (SDO). The F29 standards portfolio consisted primarily of anesthetic and respiratory equipment (ventilators, anesthesia machines, airway devices, fluid warmers, etc.). This portfolio was likely to move en masse to a new SDO and a new committee, but ICE required careful consideration of its new “home” to ensure its continued development and effective connection to an emerging portfolio of interdependent standards. The desired goal of Aim 1 of this project is to successfully identify a new standards organization and committee which could adopt and would further develop ASTM F2761 (ICE) and its future Parts (including the ICE Data Logger).

ICE Data logging – which is medical network “system-level data logging” – is essential to achieve market success of heterogeneous interoperable medical device systems, by addressing liability and quality assurance concerns, and by driving standardization of interfaces to enable data logger connectivity. The ICE standard includes an ICE Data Logger in the logical architecture, which has served as a placeholder for a future Data Logger standard. Under Aim 1 of this project, MD PnP has worked with the AAMI Interoperability Working Group to develop and submit for approval to the AAMI Standards Board, a New Work Item Proposal (NWIP) to initiate a consensus standard for an ICE Forensic Data Logger. AAMI procedure requires substantial evidence of progress toward a standard prior to submission of the NWIP. Therefore, a proposed 36-page draft ICE Data Logger standard was written by MD PnP under this award.

Our hypotheses and objectives for Option-Year 3 were:

1. That the ASTM F2761 ICE standard had reached a sufficient level of relevance to the standardization and manufacturing communities, such that it would be desirable for adoption by a new Standards Development Organization (SDO) as ASTM sunsetted Committee F29
 - Identify a new SDO, identify risks and opportunities, and shepherd a successful transition to the new SDO
2. That the foundational research and documentation on ICE Data Logging was sufficient to provide a basis for a consensus standard for ICE Data Loggers
 - Draft and submit a New Work Item Proposal for ICE Data Logging into the standardization process in AAMI, via the Interoperability Working Group
3. That there had accumulated sufficient research to convey the systems engineering relationship between interoperability, standards, and patient safety
 - Draft and submit the above for publication in a peer-reviewed journal
4. Expand the release of the Clinical Scenario Repository (CSR), also known as “Good Ideas for Patient Safety”

Transition of F2761 ICE from ASTM to AAMI. Meetings were held with senior executives of ASTM and AAMI, as well as the Executive Committee of F29, to develop a consensus plan. All ASTM F29 standards were transferred to AAMI Committee A/R (Anesthetics & Respiratory),

with the exception of ICE, which was assigned to the newly formed AAMI Interoperability Working Group (IOWG). The placement of ICE in the IOWG has enabled a number of complimentary standards to be initiated by the experts who constitute the IOWG. Dr. Goldman was appointed Co-Chair of the IOWG.

New Work Item Proposal (NWIP) for the ICE Forensic Data Logger Standard. After extensive pre-meetings, a draft NWIP for the ICE Data Logger was submitted to IOWG committee ballot. The draft data logger standard, supported by this award, was used as foundational supporting content. Following meetings and document revisions in June and July 2016, the IOWG committee unanimously approved the NWIP for submission to the AAMI Standards Board (SB), which meets biannually. Updated NWIP documents were circulated to the SB in October 2016 in preparation for their November 2016 meeting. The updated documents include a strong letter of support from Draeger.

While awaiting formal approval, AAMI has advised the IOWG committee to begin editing the draft ICE Data Logger standard. In support of this project, we set up a web-based project site (see Figure 1) and Dr. Goldman chaired virtual meetings, approximately every two weeks in June - October 2016. [Note: Five large medical device companies are actively participating in this effort.]

ICE Data Logger (Black Box Recorder)

MD PnP Program

Overview

Messages

To-Dos

Calendar

Writeboards

Chat

Time

Files

Project overview & activity

[New message](#) | [New to-do list](#) | [New event](#) | [New file](#)

This project is intended to develop create a clinical and technical foundation for an ICE Data Logger that can serve as a basis for a consensus standard for black box recording and playback for clinical environments.

TODAY

Writeboard

Meeting Notes Sept 8 2016

Updated by Julian G.

THURSDAY, 8 SEPTEMBER 2016

File

Comments on ICE DL proposed draft standard from Sept 8 2016.xlsx

Uploaded by Julian G.

File

ICE Data Logger proposed Draft Standard for NWIP – IOWG edits J...16.doc

Uploaded by Julian G.

THURSDAY, 25 AUGUST 2016

Message

Today's TCon Cancelled

Posted by Julian G.

THURSDAY, 11 AUGUST 2016

Message

ICE Data Logger meeting minutes are posted on Basecamp

Posted by Julian G.

File

Comments on ICE DL proposed draft standard from August 11 2016 r2.xlsx

Uploaded by Stan W.

Writeboard

Meeting Notes August 11 2016

Updated by Julian G.

File

Comments on ICE DL proposed draft standard from August 11 2016.xlsx

Uploaded by Stan W.

TUESDAY, 9 AUGUST 2016

File

Comments on ICE DL proposed draft standard from August 9 2016.xlsx

Uploaded by Stan W.

Figure 1. ICE Data Logger Basecamp Project

5

The deep technical analysis performed by the IOWG committee is documented in a committee-shared spreadsheet. In addition, two articles have been published recently on this work: “Capturing Essential Information to Achieve Safe Interoperability” (Weininger, Jaffe, Rausch, Goldman) in *Anesth Analg* 2016 Jul 6, and “The Importance of State and Context in Safe Interoperable Medical Systems” (Weininger, Jaffe, Robkin, Rausch, Arney, Goldman) in *IEEE Journal of Translational Engineering in Health and Medicine*, 8 July 2016.

Although our deliverable of submission of the NWIP to the AAMI process is complete, we will continue to chair standards meetings and support meeting logistics (e.g. via Basecamp) to mature the ICE Data Logger standard until the end of the period of performance of this award. We will also respond to ICE Data Logger NWIP questions, if posed by the AAMI Standards Board, and will report on the status of the November 2016 AAMI Standards Board meeting.

Expand the release of the Clinical Scenario Repository (CSR). The CSR pilot with the American Society of Anesthesiologists (ASA) Committee on Patient Safety and Education (CPSE) continued until October 2016. Results of the pilot (approximately 25 scenarios submitted by the Committee members and user feedback) were discussed at the CPSE face-to-face meeting on October 24, 2016 in Chicago, and a CPSE-authored publication is planned.

MGH pilot: The CSR will require porting to a new software environment in order to be included in the EHR/IT system used at Mass General Hospital. As we explore an Anesthesia pilot during the remainder of the period of performance of this award, we will also analyze the feasibility of the software port. We are developing a description of the feasibility of implementing the CSR in the MGH EHR/IT environment. As described above, we have met our deliverable of disseminating the description and role of the CSR in supporting safe, usable integrated medical systems.

Standards Development, Aim 3: Provide interoperability demonstrations and education at the AAMI annual meeting and standards meeting in June 2015; based on the feedback received at these meetings, refine our technology and document our findings.

Our work progress toward developing standards using OpenICE as a prototype platform for interconnectivity engineering, research, and technology has been presented to groups including UL, ASTM, the FDA Cybersecurity Guidance Council, NIST, AAMI, and NIH.

We continue to provide interoperability demonstrations and test laboratory resources through open house technical workshops and site visits, as well as education and outreach via the community forum and webinars hosted on our ICE technical site (OpenICE.info).

We provided interoperability demonstrations and education at the AAMI annual meeting and standards meeting in Denver in June 2015. OpenICE was demonstrated by MD PnP clinical engineer Jeff Peterson at an exhibit. An accompanying lecture on the Medical Internet of Things was delivered by Dr. Goldman. The AAMI venue, which our team attends regularly, provides important feedback on interoperability, system integration, and adoption from the perspectives of Clinical Engineers and Health Technology Managers. Based on the feedback received at these meetings, we updated the OpenICE.info web site with tutorial content and have been refining our technology and documenting our findings.

Clinical and Engineering Requirements

While we have transitioned into new requirements-centered aims for the purposes of this award, our early objectives of continued analysis of clinical scenarios to define detailed workflows,

clinical requirements, and related engineering requirements, and identifying appropriate use cases for use by others are supported by ongoing work. For example, the CSR project has provided a new pathway to acquire clinical scenarios in support of deriving engineering requirements. We continue to identify and refine high-level clinical scenarios, as a foundation for developing technical specifications for medical device interoperability. With DHA support, we have been able to organize requirements across multiple projects and sources that can facilitate use by the DoD, the VA, standards development organizations, and device manufacturers. We have expanded our work on use cases from the ASTM ICE standard to include ISO, IEC, AAMI, AAMI/UL, and other related standards work.

Clinical and Engineering Requirements for Safe Medical Device Interoperability, Aim 4: Implement workflow to more effectively support standards activities using our requirements tools, and demonstrate these capabilities for feedback at the next AAMI/UL JC2800 meeting in June 2015.

We implemented Serena RM, a commercial requirements management database well suited to support collaboration. We used it to incorporate the requirements we developed under our NIH grant – including generic and ICE-specific requirements, PCA-specific safety and clinical requirements and associated attributes, and collaborator comments on these requirements. We have also used Serena RM to export requirements and comments, and presented them to AAMI/UL JC2800 in the “Systems Requirements from Clinical User Perspective” document. We are using these requirements to establish the scope of the exemplar used for AAMI/UL JC2800, based on our design documentation (requirements and hazard identification).

At the December 2014 AAMI requirements week, the response to initial sharing of Serena RM requirements output was very positive, and we subsequently received renewed interest from the joint committee in utilizing our tools to aid standards development. In response, we created a demo schema and workflow within Serena RM to more closely align with the standards development work by AAMI/UL JC2800. This enables our MD PnP internal and external standards development work to continue in parallel. We demonstrated this schema and workflow to members of the AAMI/UL JC2800 team at a working session in our Lab prior to their June 2015 meeting and in on-site meetings at our program’s offices.

The implementation of requirements in Serena RM is very powerful because of the capability to export Excel documents and re-import them with tracking of edits to requirements. This enables a pathway of “crowd sourcing” requirements for use by the extended community of researchers and manufacturers – an exciting enabler of innovation. We tested a workflow based on exporting Serena RM content to Excel format, sharing the Excel document with standards committee members, and importing and tracking committee input using Serena RM’s specialized importation capabilities. While technically effective, we found that this approach may be too resource-intensive to maintain as the AAMI/UL specialized working groups proliferate.

We have provided AAMI/UL JC2800 with extensive use case materials and have used our Lab’s subject matter expertise to contribute to a wide range of committee documents. In addition, we host six AAMI/UL JC2800 committee working groups on a secure MD PnP-resourced project site (via Basecamp). The site is provided without charge to the committee, and is open to all standards development committee members to enable discussion and sharing.

The Serena RM installation used to store and share requirements as described above, is being used to document new clinical requirements for a current DoD Joint Warfighter Medical

Research Program contract related to a heat-stress clinical scenario. This demonstrates the extensibility and modularity of our research products.

Interoperability and Security Requirements for Medical Device Procurement, Aim 6: For the adoption roadmap, obtain additional input from the members of the new IEEE-ISTO ICE Alliance.

We have expanded our involvement in the medical device cybersecurity realm by building on our competency in medical device interoperability and operational biomedical/HIT cybersecurity applied to product deployment within the Partners HealthCare System. A collaborating professor at the University of Pennsylvania, Insup Lee, led a research project on authentication for OpenICE: “Protecting the interoperable clinical environment with authentication” (Medical Cyber Physical Systems '16 Vienna, Austria, c 2016 ACM, ISBN 978-1-4503-2138-9, DOI: 10.1145/1235).

In one-on-one and group meetings with medical, IT, and security companies (including founding members of the ICE Alliance), it has become evident that non-medical device companies may not have sufficient healthcare domain knowledge to efficiently contribute their cybersecurity expertise. Therefore, we are educating the community through meetings and presentations in order to promote knowledge sharing to accelerate effective healthcare cybersecurity solutions. These venues have included the Industrial Internet Consortium, IEEE EMBS, and the FDA Workshop on Collaborative Approaches to Medical Device Cybersecurity (January 2016).

The potential cybersecurity benefits of the ICE architecture for “sandboxing” devices and apps in the patient environment are also becoming increasingly clear.

We have been providing medical device interoperability domain expertise to assist the Veterans Administration in a medical device cybersecurity CRADA that the VA initiated with UL to pilot a new cybersecurity standard (UL 2900). We plan to host a VA CRADA outcomes meeting in the MD PnP Lab in 2017.

Regulatory Science for Safe Medical Device Interoperability, Aim 9: Based on the successful second FDA pre-IDE submission, respond to the FDA’s request that we formulate use cases to better convey the differences between pair-wise and component-wise interoperability.

Through extensive near-weekly meetings with the same pre-IDE MDISWG project team (Medical Device Interoperability Safety Working Group), we have nearly completed two documents. One is a response to the FDA which includes the examples that were requested, and the other document is a manuscript intended for publication in the *Journal of the Regulatory Affairs Professionals Society*.

We have worked with the FDA/CDRH on implementing a Research Collaboration Agreement (RCA) on medical device interoperability. This MGH-FDA Public Private Partnership agreement will facilitate joint projects on interoperability and sharing of regulatory science results, such as the Pre-IDE research. The five-year RCA has been fully executed.

Key Research Accomplishments

- **Standards work related to medical device interoperability.** The ICE Data Logger proposed draft standard, which was drafted under Option Year 2, was modified by the Committee and submitted to AAMI to accompany the submission of the ICE Data Logger

New Work Item Proposal (NWIP). The NWIP has been submitted to the AAMI Standards Board and the draft standard has been extensively reviewed and edited by the Interoperability Working Group committee members.

- **Clinical and Engineering Requirements for Safe Medical Device Interoperability.** Requirements for safe medical device interoperability and for data logging have been shared with the AAMI/UL Joint Committee 2800 on interoperability and with the IEC committee developing an updated standard for Pulse Oximeters. A Healthcare Task Group (co-chaired by Dr. Goldman) and a Connected Care Test Bed initiative have been formed within the Industrial Internet Consortium (IIC). Plans are in place to host the Testbed in the MD PnP Lab to provide a community forum to disseminate interoperability research findings that are applicable to products being developed for the Medical Internet of Things.
- **Interoperability and Security Requirements for Medical Device Procurement.** Security requirements based on the new UL 2900 standard, as well as the NIST security framework, are under review for inclusion in the next version of the MD FIRE procurement document for interoperable medical devices. MD PnP program interoperability research findings and subject matter expertise are being shared with the Veterans Administration to inform the VA/UL medical device cybersecurity CRADA.
- **Regulatory Science for Safe Medical Device Interoperability.** The FDA Pre-submission (formerly “pre-IDE”) on medical device interoperability, led by the MD PnP program, has informed the FDA in support of their soon-to-be-released interoperability guidance document, and is being used by medical device manufacturers in their FDA regulatory submissions.

Reportable Outcomes

Quarter 1, September 21, 2015 – December 20, 2015:

- October 2015 – December 2015 – Weekly teleconference calls of the Medical Device Interoperability Safety Working Group (MDISWG) to advance the Pre-IDE Supplement submission to FDA
- October 2015 – December 2015 – Weekly teleconference calls of the AAMI/UL JC2800 standards committee
- October 24-28 2015 – American Society of Anesthesiologists Annual Meeting, San Diego, CA; presentations and planning related to the CSR project
- November 9-10 2015 – NIH-IEEE Strategic Conference on Healthcare Innovations and Point-of-Care Technologies for Precision Medicine, Gaithersburg, MD
- November 14-17 2015 – AMIA Conference, San Francisco, CA; Nursing Informatics HIT Maker Faire featured OpenICE
- December 1 2015 – Health Information Technology IPR, Ft Detrick, MD
- December 7-11 2015 – AAMI Standards Week Conference, Newport Beach, CA

Quarter 2, December 21, 2015 – March 20, 2016:

- January 2016 – March 2016 – Weekly teleconference calls of the Medical Device Interoperability Safety Working Group (MDISWG) to advance the Pre-IDE Supplement submission to FDA
- January 2016 – March 2016 – Weekly teleconference calls of the AAMI/UL JC2800 standards committee

- January 20-21 2016 – FDA Cybersecurity Workshop, Washington, DC
- February 22 2016 – New Jersey Institute of Technology President's Forum and Faculty Research Showcase, Newark, NJ; presentation of our interoperability research and implications for the Medical Internet of Things
- February 29 – March 4 2016 – HIMSS, Las Vegas, NV
- March 8 2016 – AAMI Committee on Standards Strategy, Washington, DC

Quarter 3, March 21, 2016 – June 20, 2016:

- March 21 2016 – AAMI Interoperability Working Group (IOWG) and AAMI-UL WG03 TG01 Joint Meeting via WebEx
- April 2016 – June 2016 – Weekly teleconference calls of the Medical Device Interoperability Safety Working Group (MDISWG) to advance the Pre-IDE Supplement submission to FDA
- April 2016 – June 2016 – Weekly teleconference calls of the AAMI/UL JC2800 standards committee
- May 2-3 2016 – UL Health Council Conference, Chicago, IL
- May 16-20 2016 – ISO TC 121 US-hosted conference, Chicago, IL
- June 3-10 2016 – AAMI Annual Meeting & Standards Meeting, Tampa, FL

Quarter 4, June 21, 2016 – September 20, 2016:

- June 27-29 2016 – Council of Engineering Systems Universities (CESUN) meeting, Washington DC
- July 2016 – September 2016 – Three teleconference calls of the Medical Device Interoperability Safety Working Group (MDISWG) to advance the FDA Pre-IDE submission supplement
- July 2016 – September 2016 – Two-to-four teleconference calls/month of the AAMI/UL JC2800 standards committee
- July – September 2016 – Two teleconference calls/month of the AAMI SM-WG03 (interoperability meetings)
- August 15 2016 – MHSRS, Orlando, FL
- August 16-20 2016 – IEEE EMBS Annual Conference, Orlando, FL
- September 13 2016 – JPC-1 Medical Simulation & Information Sciences Internal Project Review, Ft Detrick, MD

Presentations on Medical Device Interoperability Topics:

Dr. Goldman delivered invited presentations on topics related to medical device interoperability for improving patient safety and healthcare efficiency to the following groups during the past year:

Quarter 1, September 21, 2015 – December 20, 2015:

- September 30 2015 – Presentation at Cybersecurity for Healthcare and Medical Devices conference
- October 24-28 2015 – American Society of Anesthesiologists, presentations at MD PnP Exhibit (1st Place Award), San Diego, CA

Quarter 2, December 21, 2015 – March 20, 2016:

- February 8 2016 – Presentation at Boston Medical Devices Summit, Boston, MA

- March 2 2016 – Presentation at HIMSS Conference, “Advancing Health Equity through Precision Medicine and HIT Innovation,” Las Vegas, NV

Quarter 3, March 21, 2016 – June 20, 2016:

- April 6 2016 – Presentation at HxR Conference, Boston, MA
- April 27 2016 – Presentation at AAMI OR Systems Engineering Conference, Washington, DC
- May 6 2016 – Invited Speaker for Grand Rounds, “The Medical Internet of Things,” Tufts Medical Center, Boston, MA

Quarter 4, June 21, 2016 – September 20, 2016:

- June 28 2016 – Keynote Lecture, “Implementing the Medical Internet of Things (MIoT) to Enable Healthcare Transformations,” Council of Engineering Systems Universities (CESUN), Washington DC
- August 15 2016 – Invited Speaker, “Integrating Medical Devices – Better Clinical Decisions – Efficient & Controlled Patient Care,” MSRS, Ft Lauderdale, FL
- August 19 2016 – MD PnP Poster Presentation at IEEE EMBS Annual Conference, Orlando, FL
- September 13 2016 – JPC-1 Medical Simulation & Information Sciences Internal Project Review, Ft Detrick, MD

Engineers from the MD PnP research team delivered the following presentations on medical device interoperability topics during the past year:

- “Software Implementation of Controllers: Hardware considerations for sensors and actuators” at FDA PCLC workshop, October 13-14 2015
- “‘The Internet of Things’ and Its Impact on Software Development for Medical Devices” at Software Design for Medical Devices 2015, October 15 2015
- OpenICE Workshop at AMIA Transdisciplinary “Maker Health Faire,” October 14 2015
- “Medical Device Interoperability and Cybersecurity” at Cybersecurity Workshop, Medical Devices Summit, February 8 2016
- “Securing Medical Cyber-Systems: Challenges and Future Directions” at ISMICT 2016, March 20-23 2016

Web Site:

- www.mdpnp.org is maintained as a major communication vehicle for the program and all major programmatic initiatives, including MD FIRE contracting language, publications, posters, links to streaming video of talks from plenary meetings and from the FDA Workshop. The OpenICE project information and downloads of sharable documents and code are located at www.openice.info.

Manuscripts/Publications:

1. Robkin M, Weininger S, Preciado B, **Goldman JM**. Levels of conceptual interoperability model for healthcare framework for safe medical device interoperability. In: Product Compliance Engineering (ISPCE), 2015 IEEE Symposium: 1-8.
2. Weininger S, Jaffe MB, Rausch T, **Goldman JM**. Capturing Essential Information to Achieve Safe Interoperability, Anesth Analg 2016 Jul 6 [Epub ahead of print]

3. Weininger S, Jaffe MB, Robkin M, Rausch T, Arney D, **Goldman JM**. The Importance of State and Context in Safe Interoperable Medical Systems. IEEE 2016; 99: 2168-2372.

Conclusions

This Option-Year has enabled significant changes to the trajectory of standards and technologies to apply interoperability in support of patient safety and innovation. Several other standards are building on the ICE standard, and will inform changes to future revisions to ICE and to the ICE Data Logger standard. (AAMI/UL JC2800 will require data logging based on requirements in the ICE Data Logger standard.)

Many companies, researchers, and government representatives have become engaged in this body of work. Several companies are developing ICE-based interoperable platforms. This progress would have been unlikely without the support of DHA. Despite the progress, gaps exist in the standards and technology, and in the knowledge roadmap. For example, basic research into Medical Device Interface Data Sheets (MDIDS) was initiated by the MD PnP Program to enable alignment of requirements for medical device communication data elements, nomenclature standards, clinical use cases, and biomedical procurement specs. As a concept based on a limited pilot project, MDIDS has gained traction as a catalyst to progress and align standards, but ongoing support for the MDIDS project is uncertain.

At the time of this report, it is anticipated that a no-cost extension to Option-Year 3 will be requested, in order to enable further work on the transition of the ICE standard from ASTM to AAMI, including the formal launch of work on the ICE Data Logger standard; additional sharing of clinical and engineering requirements for safe medical device interoperability and of interoperability and security requirements for medical device procurement; and further work on regulatory science for safe medical device interoperability and cybersecurity.

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Other relevant documents are linked to from the text of the report.